MARYLAND
HEALTH CARE
COMMISSION

Analysis of Formal Public Comments and Staff Recommendations
State Health Plan for Facilities and Services:
Home Health Agency Services
COMAR 10.24.16

March 17, 2016

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I. Introduction

The current Chapter of the State Health Plan (Plan) that is applicable to home health agency services, COMAR 10.24.08, addresses nursing home, home health agency, and special hospital-chronic care services. This new Chapter (COMAR 10.24.16), which was adopted by the Commission as proposed permanent regulations on November 17, 2015, will exclusively address home health agency (HHA) services.

COMAR 10.24.16 was developed by Commission staff with the assistance of a 2015 HHA Advisory Group, which included representatives from Maryland HHAs of varying size, geographic location, and type, as nominated by the Maryland National Capital Homecare Association (MNCHA). Other participants on the Advisory Group included a Residential Services Agency (RSA) provider, a consumer, and State and federal regulatory agencies including the Office of Health Care Quality (OHCQ), Medicaid, and the Centers for Medicare and Medicaid Services (CMS).

The HHA Advisory Group held three meetings. To facilitate discussion at the meetings, Commission staff developed and distributed a *White Paper: A New Approach for Planning and Regulatory Oversight of Home Health Agency Services in Maryland*, which provides an overview of HHA services in Maryland. Staff also provided background papers on various issues regarding HHA regulation in Maryland and nationally. Copies of the meeting agendas, *White Paper*, background papers, and summaries of meetings are posted on the Commission's website at http://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hha.aspx

Following staff's presentation of the draft HHA Chapter to the Commission at its September 2015 meeting, it was posted on the Commission's website seeking informal public comments through October 30, 2015. Informal comments were received from three organizations (Erickson Living, Maryland National Capital Homecare Association, and Maxim Healthcare Services). Staff presented its analysis of the informal comments to the Commission at its November 19, 2015 meeting. At that meeting, the Commission adopted the new HHA Chapter as proposed permanent regulations with recommendations on changes to be made prior to publication for comment. The proposed regulations were modified, as directed, and notice was published in the January 22, 2016 issue of the *Maryland Register*. During the formal comment period ending February 22, 2016, comments were received from four organizations:

- Elizabeth Cooney Care Network (Elizabeth Weglein)
- Maxim Healthcare Services (Shannon Grace Gahs)
- Virginia HealthCare Services (Hussein Ibrahim)
- Visiting Nurse Association (VNA) of Maryland (Barry Ray)

The remainder of this document provides a summary of comments received during the formal public comment period, and staff's analysis and recommendations. A complete set of the written comments received during the formal comment period on the proposed HHA Chapter is attached.

It should be noted that because parts of COMAR 10.24.08 related to HHA services were removed with the development of the new HHA chapter at COMAR 10.24.16, COMAR 10.24.08 was also posted for comment during the formal public comment period. No comments on COMAR 10.24.08 were received.

II. Summary and Staff Analysis of Formal Public Comments

.06 Certificate of Need Application Acceptance Rules: HHA Services
.11 Acquisition of a Home Health Agency

Lookback Period: COMAR 10.24.16.06C(2) and .11F(3)-(4):

.06C. Qualifications for All Applicants.
The Commission will only accept a CON application submitted by an applicant that:
. . .

(2) Has not been convicted of Medicare or Medicaid fraud or abuse within the last ten years;

.11F. Information Required to Obtain a Determination of Coverage for an HHA Acquisition.
The Commission requires the following information from the purchaser and seller of an HHA, in addition to information required under COMAR 10.24.01.03A:
...

(3) A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony within the last ten years;

(4) A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony involving Medicare or Medicaid fraud or abuse within the last ten years;

- Maxim Healthcare Services:

  Maxim expressed concern that the ten-year lookback periods "will establish an overly stringent barrier to entry for organizations that have implemented significant corrective action plans to improve institutional controls and oversight and address prior indiscretions." Maxim suggested that a six-year lookback period would better align the MHCC lookback rules with Medicare and False Claims Act (FCA) lookback timeframes...."

- VNA of Maryland:

  The VNA of Maryland voiced support for a ten-year ban on issuing a CON to an entity convicted of Medicare or Medicaid fraud or abuse, as well as for those applicants seeking to acquire an HHA.

Staff Analysis and Recommendation:

In response to Maxim's comment, staff concludes that it is not appropriate to align the six-year lookback timeframe related to reporting and returning of self-identified Medicare overpayments with the qualifying of a CON application for acceptance. CMS regulations (42 CFR Parts 401 and 405) regarding requirements for reporting and returning of self-identified Medicare overpayments refer to six years from the date the HHA received the overpayment. As noted in the Executive Summary of these federal regulations, "Creating this limitation for how far back a provider or supplier must look when identifying an overpayment is necessary in order to avoid imposing unreasonable additional burden or cost on providers and suppliers." Furthermore, the Executive Summary of the federal regulations further elaborates that "even without this final rule, providers and suppliers are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential False Claims Act (FCA) liability, Civil Monetary Penalties Law (CMPL) liability, and exclusion from federal health care programs for failure to report and return an overpayment."

Staff agrees with VNA of Maryland that a ten-year lookback period is preferable, consistent with CMS regulations (42 CFR Part 424.535) regarding conditions for revocation of enrollment in the Medicare program which refer to 10 years as the timeframe for provider exclusion, providing as follows:

> The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding **10 years,** convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. (emphasis added)

For this reason, **staff recommends** that no changes be made to the ten-year lookback period for CON applicants, found in COMAR 10.24.16.06C(2), or for an entity that desires to acquire an HHA, found in COMAR 10.24.16.11F(3)-(4).

.06 Certificate of Need Application Acceptance Rules: HHA Services

Additional Language at COMAR 10.24.16.06C(9)

C. The Commission will only accept a CON application submitted by an applicant that:

...

(9) Affirms under penalties of perjury, that none of its owners or senior management or an owner or senior management of any related or affiliated entity has within the last ten years been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime.

- VNA of Maryland

  VNA recommended expanding the provision at COMAR 10.24.16.06C(9) "to include a) an adjudication of guilt, either by a jury or judge, b) the entry of an Alford plea, c) receipt of probation before judgment, d) the payment of substantial fines or penalties in excess of $10,000,000 with or without the admission of guilt, or e) a determination of exclusion from participation in Medicare and State health care programs under 42 US Code 1320a-7, in any such case with respect to any criminal or civil charges of Medicare or Medicare [sic] fraud or abuse."

Staff Analysis and Recommendation:

Proposed regulation, COMAR 10.24.16.06C, lists several qualifications that must be met by all applicants in order for their applications to be accepted for submission. Under the language in proposed COMAR 10.24.16.06C(9), a CON application may be accepted only if an applicant affirms under penalties of perjury that no current or former owner or senior management of any related or affiliated entity has within the last ten years "been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime."

Staff concludes that current language found at COMAR 10.24.16.06C(9) encompasses the most essential scenarios for determining whether an application would qualify for acceptance, and does not agree with VNA of Maryland's comment on the necessity to expand COMAR 10.24.16.06C(9). However, **staff recommends** a non-substantive change to COMAR 10.24.16.06C(9) that reorders a clause to make the meaning clearer, as follows:

> (9) Affirms under penalties of perjury, that within the last ten years, no [none of its owners] owner or senior management or an owner or senior management of any related or affiliated entity has [within the last ten years] been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime.

Clarify Source of Survey Citations at COMAR 10.24.16.06C(3):

C. The Commission will only accept a CON application submitted by an applicant that:
...
(3) Has received at least satisfactory findings reflecting no adverse citations on the most recent two survey cycles from its respective state agency or accreditation organization, as applicable;
...
(5) Has submitted an acceptable plan of correction for any valid and serious patient-related complaint investigated over the past three years;

- Maxim Healthcare Services:

  Maxim requests clarification regarding the meaning of "as applicable," for the purposes of determining which state agency or accreditation organizations would be the appropriate source of satisfactory site survey findings reflecting no adverse citations information that would need to be identified for HHA applicants.

Staff Analysis and Recommendation:

Staff agrees with Maxim that the language should be clarified. Staff notes that the proposed regulation refers to site surveys conducted by either a state agency or accreditation organization as relevant or applicable to the type of applicant. For instance, if an applicant is a licensed HHA but is not accredited, then that HHA's state agency would be the source of information regarding adverse or unfavorable survey citations, which may include complaint investigations. However, if an applicant is a hospital or other type of health care facility that is both licensed and accredited, the sources of adverse or unfavorable survey or complaint investigation findings will include those made by both the state agency and the applicable accreditation organization.

After considering Regulation .06C(3) in light of the other qualifying criteria in Regulation .06C, staff recommends that the term "adverse citation" be clarified to be consistent with Regulation .06C(5), which evidences the Commission's concern with "serious" complaints and adverse citations, rather than with any unfavorable but relatively minor citation or finding. Commission staff has consulted with staff of the Office of Health Care Quality, who advised that it is very rare for a survey of an HHA or RSA to be "deficiency free" but also noted that HHAs and RSAs submit plans of correction that usually are accepted by OHCQ and satisfactorily completed. Thus, without the recommended clarification in .06C(3), most if not all Maryland HHAs could not qualify to file an application to expand HHA services to another jurisdiction because almost all have had surveys in the last two survey cycles that have found one or more deficiencies. Without this change, the Chapter would not be able to accomplish the Commission's goal of considering applications by high quality HHAs and other health care facilities and providers to expand or establish HHA services in new jurisdictions.

Therefore, **staff recommends** that the following non-substantive clarifying language be added to Regulation .06C(3) to address the issue raised by Maxim and to be consistent with Regulation .06C(5):

> (3) Has received at least satisfactory findings reflecting no serious adverse citations on the most recent two survey cycles from its respective state agency, [or] accreditation organization, or both, as applicable to the type of applicant;

.07 Establishment of HHA Quality Measures and Performance Levels for Applicants

Create an exception process to Star Rating threshold at COMAR 10.24.16.07C

C. Quality Measures for Non-Maryland Medicare-Certified HHAs

In order for an application to be accepted by an applicant that has any common ownership with a Medicare-certified HHA in a state other than Maryland, it shall demonstrate that:

(1) The average rating on the CMS Star Rating system of all the Medicare-certified HHAs with which it has any common ownership met or exceeded the specified rating level; and

(2) The average performance level on selected process and outcome measures from CMS' Home Health Compare for the most recent 12-month reporting period of all the Medicare-certified HHAs with which it has any common ownership met or exceeded the specified performance level.

- Maxim Healthcare Services:

  As in its informal public comments, Maxim suggests that the quality measures for licensed RSA applicants, regardless of whether or not the RSA has common ownership with an out-of-state Medicare-certified HHA, be based on demonstrated maintenance of an accredited quality assurance program. Maxim expressed concern that "the proposed regulation would unfairly set a different standard for RSAs that are part of a larger national organization, like Maxim."

  Maxim contends that OASIS measures are an inapplicable metric for Maxim's medically fragile patients requiring custodial and maintenance care as opposed to therapy and rehabilitation services. Maxim notes that providers that focus on medically fragile patients often do not receive Star Ratings (due to lack of a sufficient number of applicable patient encounters) or receive low Star Ratings scores, despite providing excellent care to patients residing in the home and avoiding care in the institutional setting.

  Maxim suggests that the establishment of "an exception process to the Star Rating threshold requirement for applicants falling into this classification under COMAR 10.24.16.07C, to allow such applicants the opportunity to explain out-of-state Home Health Star Ratings scores, after which the Commission could, at its discretion provide an exception from the minimum Star Rating requirement."

Staff Analysis and Recommendation:

The Commission considered this same suggestion before it adopted the proposed Chapter. Staff again notes that the HHA process and outcome measures selected for public reporting on Home Health Compare are endorsed by the National Quality Forum (NQF). NQF endorsement is the result of a rigorous national consensus development process. The process uses criteria designed to assess that a measure is scientifically acceptable, useable and relevant, feasible to collect, and important to national priorities. Staff concludes that use of CMS' Star Rating scores provides an objective measure of quality that compares HHAs nationwide.

For RSA providers in Maryland with Medicare-certified HHAs in another state, the proposed regulation will use the average of the individual HHA's CMS Star Rating scores. Because RSAs without any Medicare-certified HHAs have no comparable quality measures, these regulations propose to use accreditation as a proxy for providing quality services only in that situation. Staff recommends that the Commission affirm its initial conclusion that, when CMS Star Rating scores are available, such measures should be used to determine whether an application by an RSA seeking to establish HHA services in Maryland should be considered for acceptance. Staff concludes that the Commission should not establish an exception process to the Star Rating threshold requirement for RSA applicants with Medicare HHAs in other states. Such a process would be both more onerous and subjective. **Staff recommends** no change to Regulation .07C in response to this comment.

Change RSA accreditation requirement at COMAR 10.24.16.07D(1)

.07D Quality Measures for Licensed and Accredited Hospital, Nursing Home, or Maryland Residential Service Agency (RSA) Providing Skilled Nursing Services.

...

(1) In the case of a Maryland licensed RSA applicant, it has operated with an established quality assurance program that includes systematic collection of process and outcome measures, and experience of care measures and has maintained accreditation through a deeming authority recognized by Maryland's Department of Health and Mental Hygiene for at least the three most recent years;

- Elizabeth Cooney Care Network:

  Elizabeth Cooney Care Network suggests that one year of successful accreditation should be sufficient to demonstrate an RSA applicant's ability to maintain a quality assurance program, and requests that the three-year requirement for RSA applicants to maintain accreditation found at COMAR 10.24.16.07D(1) be changed to a one-year requirement.

Staff Analysis and Recommendation:

Staff concludes that because opportunities are being provided for RSAs as applicants, and since RSAs do not have a quality system like Star Ratings, we have chosen to consider accreditation as a way for RSAs to demonstrate quality care. Staff suggests that such accreditation for at least the three most recent years is necessary to demonstrate that an RSA has the ability to consistently provide and maintain quality services. For this reason, **staff recommends** no change to COMAR 10.24.16.07D(1).

.08 Certificate of Need Review Standards for HHA Services
.09 Certificate of Need Preference Rules in Comparative Reviews

Adding new CON review standard and preference rule.

- Virginia HealthCare Services:

"[A]n additional concern for the public is the extent to which third-party payers, including Medicare and Medicaid, are in the process of implementing value-based purchasing arrangements with health care provider organizations, including home health agencies, among others. Under such payment arrangements, contracted or certified providers of services are rewarded for delivering high quality, efficient and effective services at the lowest cost …."

Virginia HealthCare Services suggests that "CON applicants be required to demonstrate their administrative, financial and clinical capabilities to operate successfully under value-based purchasing arrangements" and propose adding an additional CON review standard as well as an additional preference rule.

Virginia HealthCare Services suggested that an additional CON review standard be added at COMAR 10.24.16.08L, as follows:

> An applicant shall demonstrate ongoing participation or capability to participate in value-based payment arrangements within the proposed service area that promote the utilization of efficient and effective home health agency services.

An additional preference rule also is suggested by Virginia HealthCare Services to be included at COMAR 10.24.16.09F:

> **Proven Track Record in Providing Efficient and Effective Home Health Agency Services.** An applicant that participated in value-based payment arrangements will be given a preference over an applicant that participated exclusively in conventional fee-for-service reimbursement arrangements for providing home health agency services.

Staff Analysis and Recommendation:

The proposed Chapter includes policies to promote opportunities for different types of applicants to establish HHA services in Maryland. Policy 5, found at COMAR 10.24.16.03C, states that the Commission shall "[c]ontinue to assess, and revise as needed, the qualifying factors for jurisdictions and applicants, to account for changes in the health care delivery systems, the needs of the population and HHA marketplace, and changes in quality measurement."

Maryland is one of nine states selected to participate in the seven-year demonstration study of CMS' Home Health Value-Based Purchasing (HHVBP) model that began January 1, 2016. The HHVBP model encompasses five performance years. All Medicare-certified HHAs in Maryland are required to participate in the HHVBP model. The specific goals of the model are to: (1) incentivize HHAs to provide better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home heath setting; and, (3) enhance current public reporting processes. Since this is a seven-year demonstration project that began recently, staff concludes that it is too early to evaluate results for determining how to "operate successfully" under a HHVBP model and, therefore, premature to incorporate such a requirement into a specific CON review standard or preference rule.

Staff does not recommend adding the new additional Standard L that is suggested by Virginia HealthCare Services because such a standard would apply to all types of applicants, and RSA applicants without any affiliation with a Medicare-certified HHA would be unlikely to be able to comply with this suggested additional standard. Therefore, **staff recommends** no change to proposed Regulation .08.

Consistent with its analysis, **staff recommends** no change to the Regulation .09, concluding that the new preference suggested by Virginia HealthCare Services would create a bias against RSA applicants. The existing preference rule in proposed Regulation .09C, Proven Track Record in Serving all Payor Types, the Indigent and Low Income Persons, is a rule that can be applied to all types of applicants and that addresses financial access to HHA services.